

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,

Plaintiff,

vs.

APOTEX INC. and APOTEX CORP.,

Defendants.

C. A. No. 06-164-SLR


JOINT CLAIM CONSTRUCTION STATEMENT

Pursuant to the Amended Rule 16 Scheduling Order (D.I. 85), Plaintiff MedPointe Healthcare Inc. ("MedPointe") and Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") respectfully submit this Joint Claim Construction Statement attached hereto as Exhibit A.

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EXHIBIT A

JOINT LIST OF DISPUTED CLAIM TERMS OF THE '194 PATENT

CLAIM TERM OR PHRASE	MEDPOINTE'S PROPOSED CONSTRUCTION	APOTEX'S PROPOSED CONSTRUCTION
"irritation or disorders of the nose and eye"	Rhinitis and/or conjunctivitis, including seasonal allergic rhinitis and vasomotor rhinitis. Symptoms of rhinitis include itching (also known as "pruritus"), sneezing, increased secretions (also known as "rhinorrhea"), and congestion.	Including but not limited to rhinitis and/or conjunctivitis, including seasonal allergic rhinitis and vasomotor rhinitis.
"applying directly to nasal tissues or to the conjunctival sac of the eyes"	Topical application to the nose or to the conjunctival sac of the eyes. Excludes oral and parenteral applications.	Ordinary meaning, including but not limited to application directly to mucous membranes of the nose and eye.
"azelastine and its physiologically acceptable salts"	Azelastine and salts of azelastine that are physiologically safe, effective, and tolerable, such as azelastine hydrochloride.	A salt form of azelastine capable of being administered to an animal via at least one route of administration, including but not limited to the hydrochloride salt of azelastine.
"a medicament"	A product that includes a medicinal substance that has acceptable safety, efficacy, and tolerability for use in humans.	Claim 1 – Ordinary meaning, which includes but is not limited to a formulation containing excipients, preservatives and/or active ingredients, wherein the active ingredients include at least a member selected from the group consisting of azelastine and its physiologically acceptable salts in any concentration and may also include other active ingredients, including steroids, decongestants, mast cell

CLAIM TERM OR PHRASE	MEDPOINTE'S PROPOSED CONSTRUCTION	APOTEX'S PROPOSED CONSTRUCTION
		<p>stabilizers and/or any other active ingredient commonly used in connection with treating irritation or disorders of the nose and eye.</p> <p>Claims 2-8 – same as claim 1 except as otherwise qualified in claims 2-8, respectively.</p> <p>Claim 9 – same as claim 1, except the dosage form is further limited to a formulation appropriate for spraying, including but not limited to solutions (including aqueous solutions), suspensions, and powders.</p> <p>Claim 10 – same as claim 1, except the dosage form is further limited to a formulation appropriate for application by dropping, including but not limited to solutions (including aqueous solutions), suspensions, powders, gels or ointments.</p>
<p>"the medicament contains 0.003 to 0.5% (weight/weight) of azelastine or an amount of a physiologically acceptable salt of azelastine which contains 0.003 to 0.5% (weight/weight) azelastine"</p>	<p>The medicament contains 0.003 to 0.5% (weight/weight) of azelastine or an amount of a physiologically acceptable salt of azelastine in which the weight of azelastine base is 0.003 to 0.5% of the weight of the medicament.</p> <p>Includes a 0.0033 to 0.55% (weight/volume) aqueous solution of azelastine hydrochloride.</p>	<p>Includes salts of azelastine in which the weight of azelastine base is 0.003 to 0.5% of the weight of the medicament.</p>

CLAIM TERM OR PHRASE	MEDPOINTE'S PROPOSED CONSTRUCTION	APOTEX'S PROPOSED CONSTRUCTION
"aqueous solution"	Ordinary meaning.	Ordinary meaning, which includes a formulation wherein the excipients, preservatives, and/or active ingredients are dissolved in a solvent and the solvent is water.
"solution which contains"	Ordinary meaning.	Ordinary meaning, which includes a formulation for direct application to the nasal tissues, wherein any excipients, a preservative and active ingredients are dissolved in a solvent and the preservative is either sodium-2-(ethylmercurithio)-benzoate or alkylbenzyltrimethyl ammonium chloride in the stated concentrations.
"applied by spraying"	<p>Delivering a fixed volume (typically, 50 to 150 microliters) of an aqueous solution to nasal tissues by aerosolizing that solution into a fine mist (typically with the size of most droplets falling in the range of 10 to 250 micrometers) targeted to those tissues.</p> <p>Excludes application to the eye and excludes application of drops to the nose.</p>	Ordinary meaning, including but not limited to a method of applying a formulation appropriate for spraying, including but not limited to solutions (including aqueous solutions), suspensions and powders, wherein the formulation spray delivers, for example, drops (solutions, aqueous solutions), streams (solutions, aqueous solutions, suspensions), or particles (powders, suspensions) directly to the nasal tissues or conjunctival sac of the eyes.
"allergy-related . . . symptoms"	Symptoms of rhinitis due to an IgE-mediated allergen response, including seasonal allergic rhinitis, such as rhinorrhea, nasal congestion,	Ordinary meaning, which includes, for example, symptoms commonly associated with seasonal allergic rhinitis (i.e., hay

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	sneezing, and itching of the eyes and nose.	fever).
"vasomotor or rhino-related colds or symptoms"	Symptoms of nonimmunologic, noninfectious, chronic rhinitis such as chronic nasal congestion, rhinorrhea, and sneezing.	Ordinary meaning, which includes but is not limited to vasomotor rhinitis (also known as rhinitis vasomotorica) and colds and symptoms associated with rhinoviral infection.
"applying directly to the patient's nasal tissues or to the conjunctival sac of the patient's eye"	Topical application to the nose or to the conjunctival sac of the eye. Excludes oral and parenteral applications.	Ordinary meaning, including but not limited to application directly to mucous membranes of the nose and eye.

JOINT LIST OF UNDISPUTED CLAIM TERMS OF THE '194 PATENT

CLAIM TERM OR PHRASE	PROPOSED CONSTRUCTION
"method for the treatment of"	Treatments that address symptoms and/or treatments that address the underlying cause of disease.
"sodium-2-(ethylmercurithio)-benzoate"	A preservative commonly referred to as thimerosal.
"alkylbenzyltrimethyl ammonium chloride"	A preservative commonly referred to as benzalkonium chloride.